

REMARKS/ARGUMENTS

Favorable reconsideration of this application in view of the above amendments and in light of the following discussion is respectfully requested.

Claims 1, 4-25, 30, 32-56, 71, 73-79 and 84-87 are pending, with Claims 14-16, 21, 23-25, 46-48, 53, 55, and 56 being withdrawn from consideration. Claims 1, 30, 32 and 71 are amended; Claims 2, 3, 72 and 80-83 are canceled; and Claims 84-87 are newly submitted. No new matter is introduced.

In the Office Action, Claims 1, 4-6, 13, 17-20, and 22 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang (U.S. Patent No. 6,343,717) in view of Muhar (U.S. Patent No. 6,254,294); Claims 7 and 8 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of Muhar and Zygmunt (U.S. Patent No 6,488,646); Claims 9 and 10 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of Muhar and Barabino (U.S. Patent No. 4,740,194); Claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of Muhar and Tobin (U.S. Patent No 3,792,699); Claims 30, 32, 35-38, 45, 49-52, 54, 71, 73, 74, 76, 81 and 83 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhang in view of Schindler (U.S. Patent No. 6,358,231); Claims 39, 40 and 77 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of Schindler and Zygmunt; Claims 41 and 42 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of Schindler and Barabino; Claims 43 and 44 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of Schindler and further in view of Tobin; Claims 32-35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhang in view of Schindler and Barr (U.S. Patent No. 6,812,254); Claim 75 was rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of

Schindler, Lewis, Ohsumi (US Patent No. 5,658,981); and Claims 78 and 79 are rejected under 35 U.S.C. §103(a) as unpatentable over Zhang in view of Schindler and Lewis; and Claims 1, 71, 80 and 82 were rejected under 35 U.S.C. § 103(a) as unpatentable over Zhang in view of Franks-Farah (U.S. Patent No. 6,840,379).

Applicants acknowledge with appreciation the courtesy of Examiner Foreman in conducting a personal interview with Applicants' representative on February 9, 2009. The substance of the interview is summarized hereinafter and also on the Interview Summary. During the personal interview, Applicants' representative discussed the feature of a kit that includes at least three applicators that each respectively include the same compound at three different concentrations.

Following from this discussion amended Claim 1 recites a first applicator includes a first tube containing *a first test substance* comprising a compound at *a first concentration*, a second applicator including a second tube containing *a second test substance* including the compound *at a second concentration*, and a third applicator including *a third tube* containing a third test substance including the compound at *a third concentration*. The first concentration is different from the second and third concentrations, and the second concentration is different from the third concentration.

Also following from this discussion, amended Claim 30 recites the kit includes at least three applicators, each applicator including a test substance that includes the at least one compound at concentrations varying by a factor of at least two from one applicator to another.

In addition, amended Claim 71 recites a plurality of tubes includes a first tube containing a first test substance including a compound at a first concentration, a second tube

containing a second test substance including the compound at a second concentration, and a third tube containing a third test substance including the compound at a third concentration. The first concentration is different from the second and third concentrations, and the second concentration is different from the third concentration.

Dependent Claim 81 previously recited features similar to those now recited in Claims 1, 30 and 71. The outstanding Office Action rejected Claim 81 based on the combination of Zhang and Schindler, stating “it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the substances as disclosed in Zhang et al. to include a stimulating agent in varying concentrations as taught by Schindler et al. in order to anesthetize the eye, mouth or ear of a patient as needed (Col. 1, lines 45 - 67).

However, Schindler states that “solution concentrations on the order of 0.5% Tetracaine have been used in ophthalmic applications, concentrations of 1 to 2% have been used in the mouth or nose and applied as a spray, and 0.1 to 0.5% solutions have been used in spinal or epidural applications.”<sup>1</sup> Thus, even if one were “to include within a kit a stimulating agent in varying concentrations to allow a physician to choose which stimulating agent to use in order to anesthetize the eye, mouth or ear of a patient as needed” as suggest by the outstanding Office Action, Schindler states that only requires *two* different concentrations: (1) solution concentrations on the order of 0.5% for the eye, and (2) concentrations of 1 to 2% have been used in the mouth or nose. By contrast, each of amended Claims 1, 30 and 71 require *three separate tubes* and/or *three separate applicators* that respectively include a test substance at *three different concentrations*.

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<sup>1</sup> See Schindler, at col. 1, lines 58-63.

Further, Schindler states that “concentrations of 1 to 2% have been used in the mouth or nose and *applied as a spray*.”<sup>2</sup> As Zhang describes *pipettes* and makes no mention of spraying, it is submitted that it would not be obvious to include the concentration necessary for the mouth and nose in the pipettes described in Zhang.

Moreover, it would not have been obvious include the 0.1 to 0.5% solutions that Schindler describes have been used in spinal or epidural applications because the pipettes described in Zhang are in no way suitable to perform a spinal or epidural administration of anesthetic. Nor would it be obvious to include such concentrations in a kit with concentrations used for eyes, ears, or mouth, as it is submitted that spinal or epidural applications are of such a different nature than ear, nose, and mouth applications that their inclusion in the same kit would be more likely to create physician error than enhance convenience and choice.

Accordingly, even the combined teachings of Zhang and Schindler fail to disclose or suggest all of the features of Claims 1, 30 or 71. It is submitted Claims 1, 30, 71 and the claims depending therefrom are in condition for allowance.

During the personal interview, Applicants’ representative also discussed the feature of the at least one test substance including a *stimulating agent for stimulating a peripheral nervous system*. As discussed during the personal interview, the specification as originally filed gives this phrase special meaning. In particular, paragraph [0010] of the specification as originally filed states (emphasis added) “The term ‘stimulating agent for stimulating the peripheral nervous system’ is used to designate a compound which makes it possible to

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<sup>2</sup> See Schindler, at col. 1, lines 58-63, emphasis added.

induce a sensory response connected with activating sensory and cutaneous nerves having endings that flush with the stratum corneum epidermis.”

“[D]uring examination proceedings, claims are given their broadest reasonable interpretation *consistent with the specification*.” *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, (Fed. Cir. 2000). (Emphasis added.) The court in *Hyatt* determined that although the specification was lengthy, it contained no definition of the term “shared” or “sharing” that would require the Board to construe those limitations in the narrower manner than that applied from a dictionary definition. By contrast, as noted above, the specification of the present application does provide guidance as to the meaning of a “stimulating agent for stimulating the peripheral nervous system” within the context of the present application. In particular, the present application defines this phrase as requiring a compound which makes it possible to induce a sensory response connected with activating sensory and cutaneous nerves having endings that flush with the stratum corneum epidermis. Thus, mere sensory perceptions caused by touch or a change in temperature are not sufficient to meet this limitation when recited in the claims.

Following from this discussion, Claims 84-87, which depend from Claim 1, are newly submitted. Claims 84-87 recite similar features to those recited in Claims 32-35, which depend from Claim 30. Claim 84 recites similar features to those recited in Claim 73, which depends from Claim 71. In particular, Claim 84 recites the at least one test substance comprises *a stimulating agent for stimulating a peripheral nervous system*.

Turning to the applied references, Franks-Farrah relates to a method and system for performing intermittent male catheterization. In particular, Franks-Farrah describes a system that includes tubes of lubricating gel (20), male intermittent catheters (22), antibacterial liquid

soap (24) and a tube of alcohol gel (30).<sup>3</sup> None of these substances meets the claimed *stimulating agent for stimulating a peripheral nervous system*. Indeed, Franks-Farrah relates to a urinary catheter that is to be inserted into the penis. As such, it would not be obvious to one of ordinary skill in the art to use a compound which makes it possible to induce a sensory response connected with activating sensory and cutaneous nerves having endings that flush with the stratum corneum epidermis in such an application.

The Office Action also relies on Barr for the teaching of capsaicin as the claimed stimulating agent. However, Barr states that (emphasis added) “[t]he burning side effect has also discouraged the use of capsaicin to treat other types of discomfort...”<sup>4</sup> As a solution, Barr proposes to neutralize the stimulating effects of capsaicin by adding a second ingredient that creates an analgesic effect.<sup>5</sup> Thus, at best, Barr describes the use of capsaicin in a way that would not be the claimed *stimulating agent for stimulating a peripheral nervous system*.

Thus, with respect to the rejection of dependent Claims 32-35, even the combined teachings of Zhang, Schindler and Barr fail to disclose or suggest all of the features recited in Claims 32, 33, 34 or 35. Accordingly, it is submitted that dependent Claims 32-35 are in condition for allowance.

With respect to the rejection of dependent Claims 39, 40 and 77 as obvious over Zhang in view of Schindler and Zygmunt, Zygmunt fails to cure the deficiencies in the combination of Zhang and Schindler discussed above with respect to either of Claims 30 or 71. Accordingly, it is submitted that dependent Claims 39, 40 and 77 are in condition for

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<sup>3</sup> See Franks-Farrah, at col. 4, lines 38-46.

<sup>4</sup> See Barr, at col. 2, lines 8-10.

<sup>5</sup> See Barr, at col. 4, lines 5-23.

allowance for at least the same reasons as amended Claims 30 and 71, from which they respectively depend.

With respect to the rejection of dependent Claims 41 and 42 as obvious over Zhang in view of Schindler and Barabino, Barabino fails to cure the deficiencies in the combination of Zhang and Schindler discussed above with respect to amended Claim 30. Accordingly, it is submitted that dependent Claims 41 and 42 are in condition for allowance for at least the same reasons as amended Claim 30, from which they depend.

With respect to the rejection of dependent Claims 43 and 44 as obvious over Zhang in view of Schindler and Tobin, Tobin fails to cure the deficiencies in the combination of Zhang and Schindler discussed above with respect to amended Claim 30. Accordingly, it is submitted that dependent Claims 43 and 44 are in condition for allowance for at least the same reasons as amended Claim 30, from which they depend.

With respect to the rejection of dependent Claim 75 as obvious over Zhang in view of Schindler, Lewis, Ohsumi, neither Lewis nor Ohsumi cures the deficiencies in the combination of Zhang and Schindler discussed above with respect to amended Claim 71. Accordingly, it is submitted that dependent Claim 75 is in condition for allowance for at least the same reasons as amended Claim 71, from which it depends.

With respect to the rejection of dependent Claims 78 and 79 as obvious over Zhang in view of Schindler and Lewis, Lewis fails to cure the deficiencies in combination of Zhang and Schindler discussed above with respect to amended Claim 71. Accordingly, it is submitted that dependent Claims 78 and 79 are in condition for allowance for at least the same reasons as amended Claim 71, from which they depend.

With regard to withdrawn Claims 14-16, 21, 23-25, it is respectfully requested that these claims be rejoined and allowed in accordance with MPEP §821.04, as these claims depend from Claims 1, and therefore include the subject matter recited in Claim 1, which is believed to be allowable.

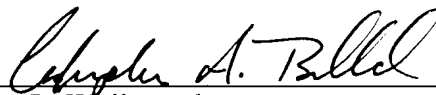
With regard to withdrawn Claims 46-48, 53, 55, and 56, it is respectfully requested that these claims be rejoined and allowed in accordance with MPEP §821.04, as these claims depend from Claim 30, and therefore include the subject matter recited in Claim 30, which is believed to be allowable.

For the reasons discussed above, no further issues are believed to be outstanding in the present application, and the present application is believed to be in condition for formal allowance. Therefore, a Notice of Allowance for Claims 1, 4-25, 30, 32-56, 71, 73-79 and 84-87 is earnestly solicited.

Should the Examiner deem that any further action is necessary to place this application in even better form for allowance, the Examiner is encouraged to contact Applicants' undersigned representative at the below listed telephone number.

Respectfully submitted,

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